



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: R.P. NARGUND et al.

Serial No. 10/730,704

Filed: December 8, 2003

For: COMBINATION THERAPY FOR THE TREATMENT OF
OBESITY

Art Unit: --

Examiner: _____

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

4. Pursuant to the waiver by the Office of the requirement under 37 CFR 1.98 (a)(2)(i) dated July 11, 2003, if the filing date of this application is after June 30, 2003, copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.

MERCK & CO., INC.

By Baerbel R. Brown Date 3/5/04

INFORMATION DISCLOSURE STATEMENT

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- ☒ the attached information is filed within three months of the filing date of the captioned case.
- ☐ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action or Notice of Allowance. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ the undersigned certifies that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ the undersigned certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,

Barbel R. Brown

By: BAERBEL R. BROWN

Attorney _____ For Applicant(s)

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Date: 3/5/04

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

COMPLETE IF KNOWN

Application Number	10/730,704
Filing Date	December 8, 2003
First Named Inventor	R.P. Nargund et al.
Group Art Unit	--
Examiner Name	

Sheet	1	of	5	Attorney Docket Number	21151
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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number	Kind Code (if known)		
			EP 0 920 864		PFIZER PRODUCTS INC.	06/09/1999
			WO 00/66578		PFIZER PRODUCTS INC.	11/09/2000
			WO 97/46250		SYNAPTIC PHARMACEUTICAL CORP.	12/11/1997
			WO 97/16189		MERCK & CO., Inc.	05/09/1997
			WO 96/40912		AMGEN Inc.	12/19/1996
			WO 97/06816		AMGEN Inc.	02/27/1997
			WO 97/18833		AMGEN Inc.	05/29/1997
			WO 98/28427		AMGEN Inc.	07/02/1998
			WO 02/060427		SEPRACOR Inc.	08/08/2002
			WO 02/060428		SEPRACOR Inc.	08/08/2002

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STATEMENT BY APPLICANT

(use as many sheets as necessary)

COMPLETE IF KNOWN**Application Number**

10/730,704

Filing Date

December 8, 2003

First Named Inventor

R.P. Nargund et al.

Group Art Unit

Examiner Name

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Sheet

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of

5

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U.S. PATENT DOCUMENTS

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FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Office	Number	Kind Code (if known)		
			WO 00/76493		NAJARIAN	12/21/2000
			WO 01/52825		NOVARTIS-ERFINDUNGEN VERWALTUNGSGESELLSCHAFT M.B.H.	07/26/2001
			WO 01/01969		ENDORECHERCHE, INC.	01/11/2001
			WO 02/32897		PFIZER PRODUCTS INC.	04/25/2002
			WO 98/18481		MERCK & CO., Inc.	05/07/1988
			WO 02/068388		MERCK & CO., Inc.	09/06/2002
			WO 02/019998		ELI LILLY AND COMPANY	03/14/2002
			WO 98/32441		SANOFI	07/30/1998
			WO 02/28346		AVENTIS PHARMA S.A.	04/11/2002

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>			COMPLETE IF KNOWN		
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Sheet	3	of	5	Attorney Docket Number	21151

NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	AA	Farrigan et al., Nature Reviews - Drug Discovery, Vol. 1 (2002), "Obesity market overview", pp. 257-258
	AB	Bray et al., Obesity Research, Vol. 7 (1999), "Sibutramine produces dose-related weight loss", pp. 189-198
	AC	Kopelman, Nature, Vol. 404 (2000), "Obesity as a medical problem", pp. 635-643
	AD	Steinbeck, Internal Medicine Journal (2002), Vol. 32, "Obesity: the science behind the management", pp. 237-241
	AE	Qu et al., Nature, Vol. 380 (1996), "A role for melanin-concentrating hormone in the central regulation of feeding behaviour", pp. 243-247
	AF	Davidson et al., JAMA, Vol. 281 (1999), "Weight control and risk factor reduction in obese subjects treated for 2 years with orlistat", pp. 235-242
	AG	Douglas et al., Int'l J. of Obesity, Vol. 7 (1983), "Plasma phentermine levels, weight loss and side-effects", pp. 591-595
	AH	Guy-Grand et al., The Lancet (1989), "Therapeutics: International trial of long-term dexfenfluramine in obesity", pp. 1142-1144
	AI	Muccioli et al., Eur. J. of Pharmacol., Vol. 440 (2002), "Neuroendocrine and peripheral activities of ghrelin...", pp. 235-254
	AJ	Chamorro et al., Int'l J. of Obesity, Vol. 26 (2002), "Appetite suppression based on selective inhibition of NPY receptors", pp. 281-298
	AK	Balasubramaniam, The American J. of Surgery, Vol. 183 (2002), "Clinical potentials of neuropeptide Y family or hormones", pp. 430-434
	AL	Guercioli, Int'l J. of Obesity, Vol. 21 (1997), Suppl. 3, "Mode of action of orlistat", pp. S12-S23
	AM	Sletten et al., Current Therap. Res., Vol. 9 (1967), "Weight reduction with chlorphentermine and phenmetrazine in obese psychiatric patients during chlorpromazine therapy", pp. 570-575
	AN	Kolakowska et al., Int'l Clinical Psychopharmacol., Vol. 2 (1987), "An open clinical trial of fenfluramine in chronic schizophrenia: A pilot study", pp. 83-88
	AO	Pierson et al., J. Med. Chem., Vol. 40 (1997), "Synthesis and biological evaluation of potent, selective, hexapeptide CCK-A agonist anorectic agents", pp. 4302-4307

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NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	AP	Bray et al., Nature, Vol. 404 (2000), "Medicinal strategies in the treatment of obesity", pp. 672-677
	AQ	Kushner et al., Current Opinion in Gastroenterology, Vol. 18 (2002), "Obesity pharmacology: past, present, and future, pp. 213-220
	AR	MacNeil et al., Eur. J. of Pharmacol., Vol. 440 (2002), "The role of melanocortins in body weight regulation...", pp. 141-157
	AS	Kirkham et al., Psychopharmacology, Vol. 153 (2001), "Synergistic effects (<i>sic</i>) of opioid and cannabinoid antagonists", pp. 267-270
	AT	Boozer et al., Metabolism, Vol. 50 (2001), "Synergy of sibutramine and low-dose leptin in treatment of diet-induced obesity in rats", pp 889-893
	AU	Wadden et al., Obesity Research, Vol. 8 (2000), "Effects of sibutramine plus orlistat in obese women following 1 year of treatment ..., pp. 431-437
	AV	Zhou et al., Society for Neuroscience Abstracts, Vol. 27 (2001), 31st annual meeting of the Society for Neuroscience, San Diego, CA, November 10-15, 2001, "Attenuation of withdrawal reaction by a selective melanocortin MC4 receptor antagonist ...", p. 599
	AW	Myrick et al., The American J. on Addictions, Vol. 10 (2001), "New developments in the pharmacotherapy of alcohol dependence", pp. 3-15
	AX	Angehelescu et al., J. of Clin. Psychopharmacol., Vol. 22 (2000), "Add-on combination and maintenance treatment ..., pp. 521-524
	AY	Matson et al., Am. J. Physiol. Regulatory Integrative Comp. Physiol., Vol. 278 (2000), "Cholecystokinin and leptin act synergistically to reduce body weight", pp. R882-R890
	AZ	Le et al., Alcohol & Alcoholism, Vol. 31 (1996), "Use of serotonin (5-HT) and opiate-based drugs in the pharmacotherapy of alcohol dependence ...", pp. 27-32
	BA	Chiesi et al., TRENDS in Pharmacological Sciences, Vol. 22 (2001), "Pharmacotherapy of obesity: targets and perspectives", pp 247-254
	BB	Atkinson et al., Obesity Research, Vol. 3 (1995), "Combined drug treatment of obesity", pp. 497S-500S
	BC	Raffa et al., Am. J. Med., Vol. 101, Suppl. 1A (1996), "A novel approach to the pharmacology of analgesics", pp. 40S-46S
	BD	Fernandez-Lopez et al., Drugs, Vol. 62 (2002), "Pharmacological approaches for the treatment of obesity", pp. 915-944

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	BE	Lu et al., Peptides, Vol. 21 (2000), "Leptin resistance in obesity is characterized by decreased sensitivity to proopiomelanocortin products", pp. 1479-1485
	BF	Dunbar et al., Brain Research Bulletin, Vol. 50 (1999), "Leptin-induced increase in sympathetic nervous and cardiovascular tone is mediated by proopiomelanocortin (POMC) products", pp. 215-221
	BG	Bickerdike et al., Eur. J. of Pharmacology, Vol. 271 (1994), "The influence of 5-hydroxytryptamine re-uptake blockade on CCK receptor antagonist effects in the rat elevated zero-maze", pp. 403-411
	BH	Proietto et al., Exp. Opin. Invest. Drugs, Vol. 9 (2000), "Novel anti-obesity drugs", pp. 1317-1326
	BI	Parker et al., Eur. J. of Pharmacology, Vol. 440 (2002), "Neuropeptide Y receptors as targets for anti-obesity drug development ...", pp. 173-187
	BJ	Rowland et al., Psychopharmacology, Vol. 159 (2001), "Effects of the cannabinoid receptor antagonist SR 141716, alone and in combination with dexfenfluramine ...", pp. 111-116
	BK	Sabath Silva et al., Revista de Investigacion Clinica, Vol. 54 (2002), "Leptina", pp. 161-165
	BL	Chaki et al., Exp. Opin. Ther. Patents, Vol. 11 (2001), "Recent advances in feeding suppressing agents...", pp. 1677-1692
	BM	Pomonis et al., The J. of Neuroscience, Vol. 17 (1997), "Interaction of the hypothalamic paraventricular nucleus and central nucleus of the amygdala in naloxone blockade ...", pp. 5175-5182
	BN	Lalonde et al, Physiol. & Behavior, Vol. 80 (2004), "Additive effects of leptin and topiramate in reducing fat deposition in lean and obese ob/ob mice", pp. 415-420
	BO	Turton et al., Nature, Vol. 379 (1996), "A role for glucagon-like peptide-1 in the central regulation of feeding", pp. 69-72
	BP	Erickson et al., Nature, Vol. 381 (1996), "Sensitivity to leptin and susceptibility to seizures of mice lacking neuropeptide Y", pp.; 415-418
	BQ	Lonnqvist et al., Nature Medicine, Vol. 1 (1995), "Overexpression of the obese (ob) gene in adipose tissue of human obese subjects", pp 950-953
	BR	De Vos et al., J. of Biol. Chem., Vol. 270 (1995), "Induction of ob gene expression by corticosteroids is accompanied by body weight loss and reduced food intake", pp. 15958-15961

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